AMERICAN IRON AND STEEL INSTITUTE, PETITIONER v. ENVIRONMENTAL PROTECTION AGENCY AND CAROL M. BROWNER, ADMINISTRATOR, U.S. ENVIRONMENTAL PROTECTION AGENCY, RESPONDENTS NATIONAL WILDLIFE FEDERATION, ET AL., INTERVENORS

No. 95-1348, Consolidated with Nos. 95-1360, 95-1362, 95-1363, 95-1378, 95-1452, 95-1483

UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

115 F.3d 979; *325 U.S. App. D.C. 76*; *1997 U.S. App. LEXIS 13744*; *44 ERC (BNA) 1769*; *27 ELR 21241*

November 22, 1996, Argued
June 6, 1997, Decided

PRIOR HISTORY: [**1] On Petitions for Review of Orders of the Environmental Protection Agency

DISPOSITION: Petitions for review are denied.

CASE SUMMARY:

PROCEDURAL POSTURE: Respondent Environmental Protection Agency (EPA) issued a Final Water Quality Guidance for the Great Lakes System pursuant to the Great Lakes Critical Programs Act of 1990, § 118(c)(2) of Clean Water Act. Petitioner American Iron and Steel Institute (AISI) sought review of the EPA order.

OVERVIEW: Because of the concern for water pollution, Congress authorized the EPA to establish guidance for the control of pollutants in the Great Lakes. EPA issued the Guidance and directed the Great Lake states to adopt standards, policies, and procedures consistent with the EPA Guidance. AISI alleged that the agency did not have statutory authority to issue the Guidance in the form of a binding regulation. AISI challenged various elements of the Guidance and alleged that the EPA was not authorized to impose uniform basin-wide criteria. The court held that the imposition of uniform basin-wide criteria was not unreasonable. The court held that the EPA had not properly considered the costs versus the benefits of eliminating bioaccumulative chemicals of concern mixing zones and that the EPA erred in establishing criteria for polychlorinated biphenyls and point-source water quality based effluent limitations for a facility's internal waste streams. The court found the EPA Guidance reasonable in all other respects.

OUTCOME: The court granted the AISI's petition and vacated the EPA Guidance governing mixing zones, the pollutant minimization program procedures, and the criteria for polychlorinated biphenyls. The court denied AISI's petition in all other respects.

LexisNexis(R) Headnotes

Administrative Law > Judicial Review > Reviewability > Jurisdiction & Venue
Civil Procedure > Jurisdiction > Subject Matter Jurisdiction > General Overview
Civil Procedure > Appeals > Standards of Review > De Novo Review
[HN1] See § 509(b)(1) of the Clean Water Act, *33 U.S.C.S. § 1369(b)(1)*.

Environmental Law > Air Quality > Emission Standards > Stationary Sources > New Sources
Environmental Law > Water Quality > Clean Water Act > Coverage & Definitions > General Overview

Environmental Law > Water Quality > Clean Water Act > Discharge Permits > Effluent Limitations
[HN2] The words "effluent limitation" in § 509(b)(1)(E) of the Clean Water Act (Act), *33 U.S.C.S. § 1369(b)(1)(E)* are defined elsewhere in the Act to mean any restriction established by a State or the Administrator on quantities, rates, and concentrations of chemical, physical, biological, and other constituents, which are discharged from point sources into navigable waters, the waters of the contiguous zone, or the ocean, including schedules of compliance. *33 U.S.C.S. § 1362(11)*.

Civil Procedure > Jurisdiction > Subject Matter Jurisdiction > Supplemental Jurisdiction > General Overview
[HN3] Questions ancillary to, or growing out of, the main action may be taken cognizance of by the court and determined, since such jurisdiction is in aid of its authority over the principal matter. The interest in assuring a forum capable of treating the case coherently justifies the comparatively modest displacement of the district court. National uniformity, an important goal in dealing with broad regulations, is best served by initial review in a court of appeals.

Environmental Law > Water Quality > General Overview
[HN4] The Great Lakes Critical Programs Act of 1990, § 118(c)(2)(A) of the Clean Water Act, directs the Administrator of the agency to publish for public notice and comment proposed water quality guidance for the Great Lakes System. Section 118(c)(2)(B) directs the Administrator to publish "final water quality guidance" in the Federal Register. Section 118(c)(2)(C) directs the Great Lakes States to adopt standards, policies, and procedures "consistent with" the guidance published by the Administrator.

Administrative Law > Agency Rulemaking > Rule Application & Interpretation > Binding Effect
Environmental Law > Water Quality > General Overview
Governments > Native Americans > Water Rights
[HN5] The final Guidance issued in accordance with the Great Lakes Critical Programs Act of 1990, § 118(c)(2) of the Clean Water Act, announced that state and tribal programs would be considered "consistent with" the Guidance if they were "as protective as" the provisions in the Guidance. *40 C.F.R. § 132.5(g)*. If a state or tribe fails to submit a plan that meets this requirement, the standards listed in the Guidance will then become applicable within that state or federal Indian reservation. *40 C.F.R. § 132.5(f)(2)*.

Governments > Legislation > Interpretation
[HN6] Congress' use of the term "guidance" is not inconsistent with a rule that incorporates a binding performance standard but leaves the states considerable flexibility in fashioning programs that meet the standard. "Guidance" can mean to give advice, or suggestions. The term is not inconsistent with the notion of mandatory regulations.

Environmental Law > Water Quality > General Overview
[HN7] Section 118 of the Clean Water Act gives the Environmental Protection Agency the authority to issue a Guidance in the form of a regulation.

Administrative Law > Judicial Review > Standards of Review > Statutory Interpretation
Civil Procedure > Appeals > Standards of Review > General Overview
[HN8] In the case of an agency's interpretation of a statute that it administers, Chevron dictates the appellate court's standard of review. Under Chevron, the agency's interpretation of "consistent with" is entitled to deference if the statute is silent or ambiguous on the matter at issue, and if the agency's interpretation is reasonable and consistent with the statutory purpose.

Environmental Law > Water Quality > General Overview
[HN9] See *40 C.F.R. § 122.44(d)(1)(vi)*.

Environmental Law > Water Quality > Clean Water Act > Discharge Permits > Effluent Limitations
[HN10] See § 402(o) of the Clean Water Act, *33 U.S.C.S. § 1342(o)*.

Environmental Law > Water Quality > Clean Water Act > Discharge Permits > Effluent Limitations
Environmental Law > Water Quality > Clean Water Act > Water Quality Standards
[HN11] The Clean Water Act (Act) requires the agency to set each effluent limitation at a level that will protect the public health and welfare, enhance the quality of water and serve the purposes of the Act, *33 U.S.C.S. § 1313(c)(2)(A)*. A pollutant may be so toxic that the discharge of even an immeasurably small amount would

have a reasonable potential to endanger the public health and welfare.

Environmental Law > Water Quality > General Overview

[HN12] It is the Environmental Protection Agency's policy that any effluent sample analyzed in accordance with the analytical method specified in the permit and other applicable procedures that is found to be below the quantification level shall be deemed in compliance with the water quality based effluent limitations.

Environmental Law > Water Quality > Clean Water Act > Coverage & Definitions > Pollutants
Environmental Law > Water Quality > Clean Water Act > Discharge Permits > Effluent Limitations

[HN13] Section 301(a) of the Clean Water Act, *33 U.S.C.S. § 1311(a)*, prohibits "the discharge of any pollutant" by any person. The "discharge of a pollutant" is defined as any addition of any pollutant to navigable waters from any point source. In order to regulate such discharges, the Congress authorized the Environmental Protection Agency in §§ 301 and 304 of the Clean Water Act to establish "effluent limitations," defined as restrictions placed upon pollutants which are discharged from points sources into navigable waters. *33 U.S.C.S. §§ 1311* and *1314*.

Environmental Law > Water Quality > Clean Water Act > Discharge Permits > Effluent Limitations

[HN14] A permitting authority may permit a bioaccumulative chemicals of concern (BCC) mixing zone provided that it first finds that the discharger is in compliance with and will continue to implement all applicable technology-based treatment and pretreatment requirements of Clean Water Act §§ 301, 302, 304, 306, 307, 402, and is in compliance with its existing national pollutant discharge elimination system water quality-based effluent limitations, including those based on a mixing zone; and the discharger has reduced and will continue to reduce the loading of the BCC for which a mixing zone is requested to the maximum extent possible. Environmental Protection Agency Procedure 3.C(6)(a)(i)-(ii).

Environmental Law > Water Quality > Clean Water Act > Discharge Permits > Effluent Limitations
Environmental Law > Water Quality > Clean Water Act > Water Quality Standards

[HN15] An national pollutant discharge elimination system permit must contain a water quality based effluent limitation for any discharge that either will cause or has the reasonable potential to cause or to contribute to an excursion above a water quality standard. *40 C.F.R. § 122.44(d)(1)*. Under Environmental Protection Agency regulations, a permitting authority must use all relevant available data, including facility-specific effluent monitoring data where available and employ procedures which account for existing controls on point and non-point sources of pollution, the variability of the pollutant or pollutant parameter in the effluent, the sensitivity of the species to toxicity testing and, where appropriate, the dilution of the effluent in the receiving water when it determines whether a pollutant discharge has the reasonable potential to cause an excursion above a water quality standard. *40 C.F.R. § 122.44(d)(1)(ii)*.

Environmental Law > Natural Resources & Public Lands > Fish & Wildlife Protection
Environmental Law > Water Quality > General Overview

[HN16] See *40 C.F.R. § 132.5(h)*.

Administrative Law > Judicial Review > Standards of Review > Abuse of Discretion
Administrative Law > Judicial Review > Standards of Review > Arbitrary & Capricious Review

[HN17] The appellate court's deference to an agency's decision is not without limits. The agency's decision will be reversed as arbitrary and capricious if there is "simply no rational relationship" between the model chosen and the situation to which it is applied. An agency must provide a full analytic defense when its model is challenged.

Administrative Law > Judicial Review > Standards of Review > Arbitrary & Capricious Review

[HN18] The appellate court will hold that an agency's use of a model is arbitrary only if it concludes that the model bears "no rational relationship" to the reality it purports to represent.

Administrative Law > Agency Adjudication > Hearings > General Overview

[HN19] An agency's failure to respond to comments is significant only insofar as it demonstrates that the agency's decision was not based on a consideration of the relevant factors. The fundamental purpose of the response requirement is to show that the agency has indeed considered all significant points articulated by the public.

Administrative Law > Judicial Review > Standards of Review

[HN20] When examining an agency's scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential.

Civil Procedure > Justiciability > Mootness > Voluntary Cessation Exception

[HN21] Voluntary cessation of allegedly illegal conduct does not deprive a tribunal of power to hear and determine the case and does not make the case moot.

COUNSEL: Fredric P. Andes, M. Cameron Davis, Corrine A. Goldstein, James N. Christman, Russell S. Frye, Kristy Bulleit and Angus Macbeth argued the cause for petitioners, with whom John H. Distin, Glenn M. Young, Theodore L. Garrett, David F. Zoll, Susan R. Connella, Stuart E. Hunt, Lee A. Casey, James Warchall and Cynthia H. Evans were on the joint briefs. Glenn P. Sugameli entered an appearance.

Mary F. Edgar, Seth M. Barsky and David L. Weigert, attorneys, U.S. Department of Justice, and Tina Kaneen and Steven M. Neugeboren, Attorneys, U.S. Environmental Protection Agency, argued the cause for respondent, with whom Lois J. Schiffer, Assistant Attorney General, U.S. Department of Justice, Jonathan Z. Cannon, General Counsel, Environmental Protection Agency, Lee C. Schroer, Assistant General Counsel, and Carol A. Siciliano, Attorney, were on the brief.

M. Cameron Davis, Corrine A. Goldstein, James N. Christman, Kristy A. Bulleit and Russell S. Frye argued the cause for intervenors American Iron and Steel Institute et al., with whom Glenn M. Young Cynthia H. Evans, Theodore [**2] L. Garrett, David F. Zoll, Susan R. Connella, Lee A. Casey and Stuart E. Hunt were on the brief. Mark C. Van Putten entered an appearance.

JUDGES: Before: GINSBURG, SENTELLE, and RANDOLPH, Circuit Judges.

OPINION

[*985] Opinion for the Court filed PER CURIAM. [1] PER CURIAM: The American Iron and Steel Institute and the National Wildlife Federation petition separately for review of the Environmental Protection Agency's Final Water Quality Guidance for the Great Lakes System. We grant the AISI's petition and vacate the Guidance insofar as it would eliminate mixing zones for bioaccumulative chemicals of concern (BCCs) and impose water quality based effluent limitations (WQBELs) upon internal facility waste streams. We also vacate the criteria for polychlorinated biphenyls (PCBs) in light of the EPA's conceded error. Petitioners' other challenges are either unripe for review or without merit.

1 Judge Ginsburg authored Parts I and V; Judge Sentelle, Parts III and VIII; and Judge Randolph, Parts II, IV, VI, and VII.

I. Background

[**3] Section 118 of the Clean Water Act (CWA) requires the EPA to promulgate Water Quality Guidance for the Great Lakes. *33 U.S.C. § 1268(c)(2)*. The Guidance must contain "numerical limits on pollutants in ambient Great Lakes waters to protect human health, aquatic life, and wildlife," as well as "minimum water quality standards, antidegradation policies, and implementation procedures." § 118(c)(2)(A). Each state in the Great Lakes System--Illinois, Indiana, Michigan, Minnesota, New York, Ohio, Pennsylvania, and Wisconsin--has two years from the date of promulgation to incorporate into its water quality standards and National Pollutant Discharge Elimination System (NPDES) permit programs provisions that are "consistent with" the Guidance, failing which the EPA is to impose such standards, policies, and procedures upon the state. § 118(c)(2)(C)

The EPA published Proposed Water Quality Guidance for the Great Lakes System on April 16, 1993. *58 Fed. Reg. 20802*. In response the agency received more than 26,000 pages of comments, data, and other information from some 6,000 interested parties. After reviewing those submissions the agency promulgated the Final Water Quality Guidance for [**4] the Great Lakes System on March 23, 1995. *60 Fed. Reg. 15366*.

II. Jurisdiction

Although all parties agree that we have jurisdiction over the petitions for review, we have independently examined the matter in order to satisfy ourselves that we may proceed. [HN1] Section 509(b)(1) of the CWA, *33 U.S.C. § 1369(b)(1)*, grants original jurisdiction to the federal courts of appeals in these terms:

> Review of the Administrator's action ... (D) in making any determination as to a State permit program submitted under *section 1342(b)* of this title, (E) in approving or promulgating any effluent limitation or other limitation under *section 1311*, *1312*, *1316*, or *1345* of this title, (F) in [*986] issuing or denying any permit under *section 1342* of this title ... may be had by any interested person in the Circuit Court of Appeals of the United States for the Federal judicial district in which such person resides or transacts business which is directly affected by such action upon application by such person.

[2]

2 All parties agree that the petitioners meet the "resides or transacts" requirement of § 509(b)(1). See AISI Brief at 13-14; NWF Brief at 7-10; EPA Brief at 35 n.20. EPA also waives any objection to venue in this court. *Id.*

[**5] [HN2] The words "effluent limitation" in § 509(b)(1)(E) are defined elsewhere in the Act to mean "any restriction established by a State or the Administrator on quantities, rates, and concentrations of chemical, physical, biological, and other constituents, which are discharged from point sources into navigable waters, the waters of the contiguous zone, or the ocean, including schedules of compliance." *33 U.S.C. § 1362(11)*. EPA's Guidance contains provisions within that statutory definition. These provisions include the Tier II methodology to derive values for additional pollutants, *40 C.F.R. pt. 132.4(c)*, the prohibition in Guidance Procedure 3.C against using mixing zones for new and existing BCC discharges, *60 Fed. Reg. at 15,417, 40* C.F.R. pt. 132, App. F, Proc. 3.C, the mercury criteria and the PCB criteria. 40 C.F.R. pt. 132, Tables 3 and 4. AISI challenges each of these effluent limitations.

It is true that § 118 of the Act, the section directing EPA to publish the Guidance, is not one of the provisions listed in § 509(b)(1)(E). However, § 118 directs EPA to promulgate the Guidance "pursuant to this section and the Administrator's authority under this chapter." § 118(c)(2)(B). [**6] In compliance with this directive, the Guidance states that "the Great Lakes States and Tribes shall adopt requirements applicable to waters of the Great Lakes System for the purposes of sections 118, 301, 303, and 402 of the Clean Water Act that are consistent with" the provisions of the Guidance. *40 C.F.R. § 132.4*. Section 301, *33 U.S.C. § 1311*, entitled "Effluent limitations," is specifically mentioned in § 509(b)(1)(E). We therefore have jurisdiction over the portion of the Guidance containing effluent limitations. See *NRDC v. EPA, 218 U.S. App. D.C. 9, 673 F.2d 400, 405 (D.C. Cir. 1982)*; *Crown Simpson Pulp Co. v. Costle, 445 U.S. 193, 196-97, 63 L. Ed. 2d 312, 100 S. Ct. 1093 (1980)*.

AISI challenges other parts of the Guidance not specified for direct judicial review under § 509(b)(1). Nonetheless we have jurisdiction to pass upon them. As we held in *Morrow v. District of Columbia, 135 U.S. App. D.C. 160, 417 F.2d 728, 737-38 (D.C. Cir. 1969)*, "[HN3] questions ancillary to, or growing out of, the main action ... may be taken cognizance of by the court and determined, since such jurisdiction is in aid of its authority over the principal matter" (internal quotation omitted). The magnitude and technical character of the record in this case strongly militates [**7] against splitting the case into pieces. *See E.I. duPont deNemours & Co. v. Train, 430 U.S. 112, 128* & n.18, *51 L. Ed. 2d 204, 97 S. Ct. 965 (1977)*. The interest in "assuring a forum capable of treating the case coherently might justify the comparatively modest displacement of the district court." *International Brotherhood of Teamsters v. Pena, 305 U.S. App. D.C. 125, 17 F.3d 1478, 1482 (D.C. Cir. 1994)*. And "national uniformity, an important goal in dealing with broad regulations, is best served by initial review in a court of appeals." *NRDC, 673 F.2d at 405* & n.15. Since most of the case is within our direct jurisdiction, we can properly assert ancillary jurisdiction over the remainder.

III. Statutory Authority

Petitioners argue that the EPA exceeded its statutory authority under § 118 of the Clean Water Act. They contend that § 118 authorized the agency to do no more than issue suggestions that the states could then decide whether to follow. They characterize the agency Guidance as "an inflexible regulatory mandate" that is far beyond § 118's limited grant of authority. Brief for Petitioners at 10. They present this argument in the form of four specific challenges to the Guidance. We reject each of the four.

A. [**8] Issuing a Binding Regulation

[HN4] The Great Lakes Critical Programs Act of 1990, Pub. L. No. 101-596, 104 Stat. 3000, [*987] modified § 118 of the Clean Water Act, adding § 118(c)(2) in its present form. Section 118(c)(2)(A) directs the Administrator of the agency to "publish ... for public notice and comment proposed water quality guidance for the Great Lakes System." Section 118(c)(2)(B) directs the Administrator to publish "final water quality guidance" in the *Federal Register*. Section 118(c)(2)(C) directs the Great Lakes States to adopt standards, policies, and procedures "consistent with" the guidance published by the Administrator.

The agency responded to these statutory commands by initiating rule-making proceedings. It issued a comprehensive proposed Guidance in April 1993. During the public comment period it received comments from over 6,000 persons and entities. It then issued a final Guidance in March 1995. [HN5] The final Guidance announced that state and tribal programs would be considered "consistent with" the Guidance if they were "as protective as" the provisions in the Guidance. *40 C.F.R. § 132.5(g)*. If a state or tribe fails to submit a plan that meets this requirement, the [**9] standards listed in the

Guidance will then become applicable within that state or federal Indian reservation. *Id.* at *§ 132.5(f)(2)*.

Petitioners' first contention is that the agency did not have statutory authority to issue the Guidance in the form of a binding regulation. They argue that by using the term "guidance" in the statute Congress intended that the agency issue nothing more than an informal advisory document.

The agency's initial response is that petitioners do not have standing to bring this claim. The agency notes that the Guidance itself is not enforceable against any party. It will become enforceable only if it is adopted by a state or imposed by the agency on a state that fails to submit an acceptable plan. Given this, the agency says it is impossible for the petitioners to have suffered any injury from the agency's choice of procedure in issuing the Guidance. It relies on *NRDC v. EPA, 306 U.S. App. D.C. 43, 1994 U.S. App. LEXIS 10129, 22 F.3d 1125, 1146-47 (D.C. Cir. 1994)*, in which we denied standing to a petitioner to challenge an agency decision to issue a new program in the form of a final rule rather than as an informal advisory document.

There is, however, a crucial difference between the case before [**10] us and *NRDC*. In *NRDC* the statute in question directed the agency to " '[]publish ... guidance' " for the design of state vehicle inspection and maintenance programs. *Id. at 1146* (quoting *42 U.S.C. § 7511a(a)(2)(B)(ii)*). The statute then directed the states to " 'comply in all respects' " with the guidance that the agency published. *Id.* (quoting *42 U.S.C. § 7511a(c)(3)(B)*). The form in which the agency published its guidance, then, had absolutely no effect on the path that a particular state would follow. No matter how the agency issued its guidance, the states were required by the statute to "comply in all material respects."

The situation in this case is different in a subtle but significant way. Section 118 does not on its face provide such a clear limitation on the flexibility of the states. In § 118 Congress directed the agency to publish guidance, and then required the states to adopt standards, policies, and procedures "consistent with" the agency's guidance. § 118(c)(2)(C). The agency was given authority for deciding whether a particular plan was acceptable. *Id.* The agency elected to respond to the statute by conducting a rule-making rather than [**11] issuing an informal advisory document. The resulting rules provide minimum standards that states must meet. *See, e.g., 40 C.F.R. § 132.5(g)*. The decision to proceed by rule-making rather than informal guidance therefore results in a greater restriction of the states' flexibility to craft their own water quality programs. This reduced flexibility limits petitioners' potential achievement in the proceedings before the various states. This is an injury sufficient to confer standing on them to challenge the agency's decision to proceed by rule-making rather than informal guidance, unlike the claimed injury in *NRDC* which sprang from the initial decision of Congress rather than the form of decision-making chosen by the agency.

However, on the merits of the question, petitioners do not fare so well. It is clear that § 118 gave the agency the authority to [*988] proceed as it did. Petitioners protest that the agency had no authority to promulgate a binding regulation. We note first that it is not clear that the Guidance can properly be characterized as a binding regulation. It certainly restricts state flexibility, but it does not immediately impose any requirements. It merely announces [**12] the standards by which state submissions will be judged and informs the states of the default rule that the agency will apply if a state submits a nonconforming plan. *Id.* at *§ 132.5*.

Regardless of how the Guidance is characterized, it is clear that Congress gave the agency the authority to issue the Guidance in this form. In previous cases we have held that Congress's use of the term "guidance" does not preclude an agency from doing what the agency did here. *NRDC, 22 F.3d at 1147* ("[HN6] Congress' use of the term 'guidance' is not inconsistent with a rule, like this one, that incorporates a binding performance standard but leaves the states considerable flexibility in fashioning programs that meet the standard."); *Public Citizen v. NRC, 284 U.S. App. D.C. 41, 901 F.2d 147, 154* (D.C. Cir.) (" 'Guidance' certainly can mean, in ordinary parlance, to give advice, or suggestions. The term is not inconsistent with the notion of mandatory regulations."), *cert. denied, 498 U.S. 992, 112 L. Ed. 2d 546, 111 S. Ct. 536 (1990)*. The statute in this case commands the agency to "specify numerical limits on pollutants" and provide guidance on "minimum water quality standards." § 118(c)(2)(A). It is unlikely that Congress would have directed [**13] the agency to set these limits and standards without also intending to allow the agency to enforce them against the states.

The use of the term "guidance" in this statute is analogous to Congress's use of the term "guidelines" in the Sentencing Reform Act. *28 U.S.C. § 994(a)(1)*. In the Sentencing Reform Act Congress gave the Sentencing Commission the authority to issue "guidelines." The guidelines the Commission issued restricted the sentencing flexibility of the federal courts. The structure of the Critical Programs Act is identical. In § 118 Congress gave the agency the authority to issue "guidance." The Guidance the agency issued restricts the flexibility of the states. We hold that [HN7] § 118 gives the agency the authority to issue the Guidance in the form of a regulation.

The agency asserts in the alternative that it had authority under § 501(a) of the CWA to issue the Guidance in this form. *33 U.S.C. § 1361(a)* (giving Administrator authority "to prescribe such regulations as are necessary to carry out his functions under this chapter"). Given that we hold that the agency had the authority to do so under § 118, we need not construe § 501(a).

B. Interpretation of "Consistent [**14] With"

Section 118(c)(2)(C) states that within two years after the agency's guidance is published, "the Great Lakes States shall adopt water quality standards, antidegradation policies, and implementation procedures ... which are consistent with such guidance." The Guidance as published provides that the agency will consider state or tribal programs "consistent with" the Guidance if they are "as protective as" the Guidance itself. *40 C.F.R § 132.5(g)*. Petitioners contend that this is an impermissible interpretation of the language of the statute. We disagree.

[HN8] Because this is a case of an agency interpreting a statute that it administers, *Chevron U.S.A., Inc. v. NRDC, 467 U.S. 837, 81 L. Ed. 2d 694, 104 S. Ct. 2778 (1984)*, dictates our standard of review. Under *Chevron,* the agency's interpretation of "consistent with" is entitled to deference if the statute "is silent or ambiguous on the matter at issue, and if [the agency's] interpretation is reasonable and consistent with the statutory purpose." *NRDC v. Reilly, 298 U.S. App. D.C. 88, 976 F.2d 36, 40 (D.C. Cir. 1992)* (quotations and citations omitted). It is clear in this case that both of these conditions have been met.

First, the statute is ambiguous on this precise question. [**15] It does not specify what level of conformity is required for a state plan to be considered "consistent with" the agency's guidance. Read naturally, the phrase is susceptible to a number of sensible interpretations. The agency's interpretation is certainly within this range.

Given that the statute does not answer the precise question, we must defer to the agency's [*989] interpretation so long as it is "reasonable and consistent with the statutory purpose." *Id.* It is clear that this interpretation passes this test. Other language in the statute requires that the Guidance "specify numerical limits on pollutants" and "provide guidance on ... *minimum* water quality standards." § 118(c)(2)(A) (emphasis added). The agency could reasonably construe this language to suggest that Congress was attempting to create a uniform set of requirements for water pollution in the Great Lakes. This goal would be defeated if the agency approved plans that were not "as protective as" the "minimum ... standards" given in the Guidance. The agency's interpretation of "consistent with" is therefore "reasonable and consistent with the statutory purpose." *Reilly, 976 F.2d at 40*. We reject petitioners' [**16] contrary arguments and uphold the agency's interpretation.

C. Imposition of Uniform Basin-Wide Criteria

The Guidance establishes four sets of water quality criteria. These criteria are made uniformly applicable to the "waters of the Great Lakes System." *40 C.F.R. § 132.3*. Petitioners argue that § 118 does not justify this imposition of uniform basin-wide criteria.

Chevron also governs this challenge. As noted above, the agency's interpretation is entitled to deference under *Chevron* if the statute is silent or ambiguous on the interpretive question and the agency's interpretation is reasonable.

As for the first step, the statute does not answer the question. Section 118 provides no explicit direction on whether the required standards may be imposed basin-wide. As for the second step, the agency's interpretation is at least a reasonable, if not indeed the most likely, interpretation. The statute calls on the agency to "specify numerical limits on pollutants in ambient Great Lakes waters" and "provide guidance on ... minimum water quality standards ... for the Great Lakes System." § 118(c)(2)(A). It is not unreasonable for the agency to interpret the statute as contemplating [**17] that it will establish uniform standards for the basin as a whole. Establishing uniformity across the Great Lakes seems to have been one of the primary purposes of the statute. The agency was therefore justified in developing and imposing basin-wide standards. Petitioners' arguments to the contrary are without merit.

D. Site-Specific Wildlife Criteria

Petitioners also challenge the procedures for site-specific modifications to the wildlife criteria. The Guidance states that "less stringent site-specific modifications to wildlife water quality criteria may be developed when a site-specific bioaccumulation factor (BAF) is derived which is lower than the system-wide BAF derived under appendix B of this part." Procedure 1.A(2)(b). Petitioners claim that the Guidance unlawfully restricts the authority of the states because it allows modifications only where the State has established a lower BAF for a particular site. A BAF is the ratio of the concentration of a contaminant in fish tissue to the concentration of the chemical in the ambient water. Petitioners contend that the agency should allow the development of site-specific criteria on other legitimate grounds.

The agency responds [**18] that the petitioners have misinterpreted the Guidance. In its brief the agency appears to interpret the regulation to allow the develop-

ment of site-specific modifications on grounds other than a lower BAF:

> EPA's intent is *not* to preclude development of site specific wildlife criteria on other scientifically-justified grounds besides site-specific bioaccumulation factors, but rather to ensure that, if site-specific criteria modifications are developed on other grounds, (1) calculation of the site-specific criteria will *also* reflect a site-specific bioaccumulation factor and (2) there will be no off-site impairment of designated uses.
>
> Respondent's Brief at 51. This is a permissible reading of the regulation, and we will hold the agency to it. So long as the agency adheres to this reading, the petitioners' challenge to these procedures is not ripe. Should the agency ever adopt the interpretation the petitioners describe, this court will of course have jurisdiction to revisit the issue.

[*990] IV. Tier II

AISI challenges the Guidance's so-called "Tier II methodology" for aquatic life and human health. But it never bothers to tell the court exactly what this Tier II [**19] methodology is. Everything is presented in the most abstract form. AISI contrasts Tier II with "Tier I," and complains about the difference, without pausing to explain exactly how Tier I functions in this complex regulatory system. We are treated to sentences like this: "Evidence shows that Tier II values derived from limited data are poor predictors of Tier I criteria from a complete database." AISI Brief at 35. And this mouthful: "EPA's wholesale use of safety factors in place of sound science, without adequate justification based on evidence of risk, further magnifies the Tier II methodology's inherent inadequacies and results in highly conservative values that are arbitrary and unjustified." *Id.* We assume the author of these sentences understands them. Perhaps so do those thoroughly versed in the intricacies of the Clean Water Act, in its regulatory jargon, in mathematics, in toxicology, in biology, oncology and so on. Too bad AISI did not take the trouble to educate the court. The first rule of advocacy is to make your argument understandable.

Not until we reach page 101 of EPA's responsive brief do we begin to get an inkling of what is bothering AISI. We will try to explain. [**20] The centerpiece of the CWA is the NPDES permitting program. *33 U.S.C. §§ 1311(a), 1342.* Pollutants cannot be discharged into the waters of the United States unless the discharger has an NPDES permit. Each permit contains discharge limitations depending on levels of pollution-control technology, and--this is the significant part for our purposes--any more stringent limitations necessary to protect the quality of the receiving waters. *§ 1311(b)(c).* But what is necessary to protect water quality? The answer lies in "water quality standards" which contain, among other things, "criteria" setting forth the legally permissible amounts of pollutants in a particular water segment. *See EPA v. State Water Resources Control Bd., 426 U.S. 200, 96 S. Ct. 2022. 48 L. Ed. 2d 578 (1976).* Now we are getting closer to this case. For it seems that all of the Great Lakes states have at least some of what are called "narrative criteria" in their water quality standards. "No toxic pollutants in toxic amounts" is only the example either party offers us. Here are a few others: waters shall be free of "substances that will cause the formation of putrescent or otherwise objectionable bottom deposits"; waters shall be free of "materials [**21] that cause odor, color or other conditions in such a degree as to cause a nuisance"; and waters shall be free from "substances in concentrations or combinations harmful or toxic to humans or aquatic life." U.S. Environmental Protection Agency, Criteria and Standards Division, Standards Branch, State Water Quality Standards For Toxics 2 (Oct. 1984). There is another type of "criterion" in water quality standards--one containing a numerical limitation on the concentration of a particular pollutant in the water. For example, waters shall not contain more than 200 fecal coliform per 100 milliliters.

Because narrative criteria do not specify numerical limitations on the concentration of a particular pollutant in the

water, a problem arises when it comes to formulating discharge limitations in permits. We have already mentioned that permits must incorporate discharge limitations necessary to ensure that the water quality standards are met. This requirement applies to narrative criteria as well as to criteria specifying maximum amounts of particular pollutants. And so the problem is how one derives numerical values from general, non-numerical narrative criteria. EPA has addressed the problem [**22] in the past. It promulgated *40 C.F.R. § 122.44(d)(1)(vi)* to deal with it on a national basis. That regulation sets forth three broadly-defined methods to translate narrative criteria into numerical values. [3] We upheld these methods [*991] as "reasonable, authorized attempts at necessary gap-filling in the CWA statutory scheme." *See American Paper Inst. v. EPA, 302 U.S. App. D.C. 80, 996 F.2d 346, 348 (D.C. Cir. 1993).*

3 [HN9] The regulation provides that the permit writer "must establish effluent limits using one or more of the following options: (A) Establish effluent limits using a calculated numeric water quality criterion for the pollutant which the permitting authority demonstrates will attain and maintain applicable narrative water quality criteria and will fully protect the designated use ... or (B) Establish effluent limits on a case-by-case basis, using EPA's water quality criteria, published under section 307(a) of the CWA ... or (C) Establish effluent limitations on an indicator parameter for the pollutant of concern...." *40 C.F.R. § 122.44(d)(1)(vi).*

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For the Great Lakes, EPA took a different approach. Section 118(c)(2) required EPA to include in the Guidance "numerical limits on pollutants in ambient Great Lakes waters to protect human health, aquatic life, and wildlife." The Great Lakes Initiative Committees, on whose work EPA relied, developed things known as translator methodologies to convert narrative criteria into numerical values. *58 Fed. Reg. at 20,835.* EPA's endorsement of this approach resulted in the Guidance's "two-tiered system," which is a fancy way of saying that if you cannot use the first method (Tier I) to do the translating because there is not enough scientific data available, then use the second method (Tier II). Both Tier I and Tier II use complicated equations to do the translating. We do not pretend to understand the mathematics.

The difference between Tier I and Tier II is in the amount of toxicological data. 40 C.F.R. pt. 132, App. A. To use Tier I, there must be a rather comprehensive set of such data. Tier II, the fallback, requires significantly less. EPA's Guidance contains a Tier I and a Tier II for the protection of aquatic life, [4] and a Tier I and a Tier II for the protection of human life. [**24] [5] Wildlife gets only a Tier I for translating words into numbers.

4 For aquatic life, the Tier I minimum data are results "of acceptable acute (or chronic) tests ... with at least one species of freshwater animal in at least eight different families"; "acute-chronic ratios ... with at least one species of aquatic animal in at least one species of aquatic animal in at least three different families provided that of the three species" one is fish, one is an invertebrate and one is an acutely sensitive fish. 40 C.F.R. pt. 132, App. A.III; *see also 58 Fed. Reg. at 20,850.* Without such data, Tier II methodology must be used pursuant to sections XII through XVII of Appendix A to 40 C.F.R. pt. 132. In deriving a Tier II value, States must, at a minimum, use at least one study of a pollutant's acute effects, and "depending upon the number of Tier I minimum data requirements satisfied in the database, different adjustment factors are applied to the lowest Genus Mean Acute Value to arrive at the Secondary Acute Value (SAV). These adjustment factors are intended to relate the results of one to seven

toxicity tests to a [Final Acute Value]." *58 Fed. Reg. at 20,855*. EPA developed these "uncertainty" factors by using specially selected samples of acute values obtained from datasets contained in the criteria documents. Analyses of Acute and Chronic Data for Aquatic Life at v. The "uncertainty" factor is inversely proportional to the amount of data that is available; "as more data become available, the derived Tier II values tend to become less conservative." *60 Fed. Reg. at 15,373*; *see also* 40 C.F.R. pt. 132, App. A.XII, Table A-1. The methodology also requires the calculation of an acute-chronic ratio, which the Guidance defines as "a standard measure of the acute toxicity of a material divided by an appropriate measure of the chronic toxicity of the same material under comparable conditions." *40 C.F.R. § 132.2*. The Guidance directs that a default acute-chronic ratio of 18 to be used if fewer than three experimentally-derived acute-chronic ratios exist. 40 C.F.R. pt. 132, App. A.XIII; *see also 58 Fed. Reg. at 20,856*. The final Tier II value is calculated as a function of both the acute value as well as the acute-chronic ratio. *Id.* EPA summarizes the approach by stating, "the Tier II methodology proposed employs all appropriate toxicity data available for a pollutant, uses statistically derived adjustment factors based on existing National criteria, and produces values which are generally conservative relative to a comparable Tier I criterion." *58 Fed. Reg. at 20,856*.

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5 The Tier II methodology for protecting human health kicks in when there is not enough Tier I data. All available data is to be considered, and uncertainty factors are to be applied to account for a less extensive database. 40 C.F.R. pt. 132, App. C.II.A.2, C.II.B.2. The methodology allows the use of shorter-duration studies and incomplete data because it utilizes "appropriate uncertainty factors to account for a less extensive database." *Id.* at C.II.B.2. The Tier II values are designed to be more conservative for carcinogens and noncarcinogens alike. The "uncertainty" factors to be applied "reflect[] a case-by-case judgment by experts" regarding the quality of available data. Great Lakes Water Quality Initiative Technical Support Document for Human Health Criteria and Values at 34-35; 40 C.F.R. pt. 132, App. C.III.B.4.

Why have this two-tiered system? EPA explained that it would bring about greater uniformity throughout the Great Lakes States. Already, EPA reported, some Great Lakes States were using a similar approach. And "EPA and the States determined that there is a need to regulate [**26] pollutants more consistently in the Great Lakes System when [*992] faced with limited numbers of criteria." 69 Fed. Reg. at 15,373.

At long last we come to AISI's complaint. It has no problem with what EPA did to protect wildlife. But with respect to the Tier II methodologies for aquatic life and human health, AISI says EPA exceeded its regulatory authority and had no scientific support for what it promulgated.

As to EPA's authority, AISI's point is that the Tier II methodologies do not fit within the statutory framework of the national Clean Water Act program. But this seems to us to ignore § 118(c)(2). That provision authorizes EPA to promulgate the Guidance and to "specify numerical limits on pollutants in ambient Great Lakes waters to protect human health, aquatic life, and wildlife ...." § 118(c)(2)(A). That is what the Tier II exercise does. If Congress had considered the existing Clean Water Act provisions sufficient to protect the Great Lakes, it is difficult to understand why it enacted § 118(c)(2). The provision was added by the Great Lakes Critical Programs Act of 1990 ("Critical Programs Act"), Pub. L. No. 101-596, 104 Stat. 3000-3004. The

Senate Report on the legislation [**27] states that § 118(c)(2) was meant "to assure the adoption of more uniform, enforceable water quality standards for the Great Lakes." S. REP. NO. 101-339, at 12 (1990). The House Report said the same. *See* H.R. REP. NO. 101-605, pt. 2, at 35 (1990). EPA found that States were using "different 'translator' methodologies in developing derived numeric criteria for implementing narrative water quality criteria," *58 Fed. Reg. at 20,835*. The Tier II methodology moves the Great Lakes States toward greater uniformity, apparently with their consent, and this is one of the things § 118(c)(2) sought to accomplish. As such, this portion of the Guidance was within EPA's authority.

On the subject of science, AISI tells us that the Tier II methodology is scientifically flawed, and constitutes an unexplained fundamental departure from prior EPA policy. We disagree with AISI on both counts. EPA adequately explained its adoption of the methodology. It stated, in response to comments, "the minimum data required for the Tier II methodology promotes consistency in how [§ 303(c)(2)(B)] is implemented. The Tier II method provides a standardized process for utilizing available data to derive values [**28] for purposes of interpreting narrative standards, thereby achieving greater consistency among the States in this activity." EPA Response to Comments Doc. No. D2791.103. EPA repeated this in the preamble to the final Guidance. *60 Fed. Reg. at 15,373*. EPA thus spelled out its objective, and even though we may not fully grasp exactly how the mechanisms work, AISI gives us no reason to doubt that EPA's means accomplish its ends. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 57, 77 L. Ed. 2d 443, 103 S. Ct. 2856 (1983)*; *Pittsburgh Press Co. v. NLRB, 298 U.S. App. D.C. 177, 977 F.2d 652, 655 (D.C. Cir. 1992)*.

AISI's "inadequate science" argument is that "by definition, Tier II values are created only where Tier I criteria cannot be calculated because sufficient data are unavailable." AISI Brief at 32. Inadequate data, however, do not mean inadequate science. AISI ignores statutory requirements. Section 118(c)(2) requires EPA to specify numerical limits on pollutants in the Great Lakes; it does not single out only those pollutants whose toxicity has generated a full set of data so that Tier I is satisfied. NPDES permits for point sources must contain discharge limitations necessary to protect water quality. [**29] Section 301 "imposes this strict requirement as to all standards--i.e., permits must incorporate limitations necessary to meet standards that rely on narrative criteria to protect a designated use as well as standards that contain specific numeric criteria for particular chemicals." *American Paper Inst., 996 F.2d at 350*. To the extent AISI supposes that no numerical limits are acceptable in the absence of a full set of data, it is very much mistaken. And it is mistaken too in thinking that EPA's methodology is "by definition" scientifically inadequate.

It is true that a Tier II aquatic health value possibly might be calculated from as little as a single acute test for a single species. *See* 40 C.F.R. pt. 132, App. A.XII. It [*993] is true as well that EPA's Science Advisory Board expressed concern about a Tier II value being derived from a single acute test for a single species. AISI Brief at 34; An SAB Report: Evaluation of the Guidance for the Great Lakes Water Quality Initiative 14 (Dec. 1992). But the Board also stated that "from a statistical perspective, the historical data base is probably scientifically defensible to account for many of the sources of toxicological testing [**30] uncertainty." SAB Report at 14. EPA answered that "although a Tier II value may be developed using a single data aquatic toxicity test, EPA believes that few, if any, Tier II values, based on a single data point, would be derived for use in control mechanisms," since the Tier II approach "requires States and Tribes to use as many acceptable data as exist." *58 Fed. Reg. at 20,855*. Given that the CWA requires that permit limits be set for any pollutant that may contribute to a violation of a narrative criteria, *American Paper Inst., 996 F.2d at 350*, the best scientific approach that determines a value is permissible. The proper question is not

whether using Tier II produces results as good as Tier I. What is the alternative when one cannot use Tier I? AISI lists other options, but it has not even attempted to convince us that these are superior to EPA's methodology. AISI Brief at 38.

AISI has another complaint about Tier II, listed in a few lines of its brief--that EPA's methodology results in large safety margins and hence conservative numerical values. *Id.* But it is within EPA's discretion to decide that in the wake of uncertainty, it would be better to give the values a conservative [**31] bent rather than err on the other side. The "uncertainty" factors do not, in any event, appear arbitrary to us. The human health uncertainty factors are created as a function of the available data. The aquatic uncertainty factors are scaled--"as more data become available, the derived Tier II values tend to become less conservative." *60 Fed. Reg. at 15,373*; *see also* 40 C.F.R. pt. 132, App. A.XII, Table A-1. The fact that permit limits derived by the Tier II methodology may be more stringent than those yielded by Tier I does not mean that EPA's promulgation of the methodology is arbitrary or capricious. Our decision in *Leather Industries of America, Inc. v. EPA, 309 U.S. App. D.C. 136, 40 F.3d 392 (D.C. Cir. 1994)*, does not assist AISI. We did not there construe § 118. Instead we held only that "a margin of safety must be rooted in an analysis of risk." *40 F.3d at 400*. The Tier II methodology, by scaling the uncertainty factors to reflect existing data, properly correlates risk with knowledge. [6]

6 In a short paragraph in its brief, AISI asserts that CWA § 402(*o*)(1), *33 U.S.C. § 1342*(*o*)(1), the "anti-backsliding" provision, "magnifies the flaws in the Tier II methodology." AISI Brief at 37. Since we find no legal flaws, that is enough to dispose of AISI's assertion. Besides, EPA interprets § 402 to allow later relaxation of a Tier II value so long as the limit has not yet become effective. The Guidance allows dischargers to obtain a two-year postponement of the effective date of any permit limit based on a translation of a narrative criteria by the Tier II methodology. Procedure 9.C; Supplementary Information Document (SID) at 40. Thus, if additional toxicity data is developed in this time period, permit revisions can be sought. Moreover, when anti-backsliding requirements do apply (*e.g.* when effluent limitations based on Tier II values change after the compliance date), § 402(*o*) allows relaxation of water quality-based limits if the requirements of either § 402(*o*)(2) or § 303(d)(4) are met. *See 58 Fed. Reg. at 20,837*. [HN10] Section 402(*o*) states that "in the case of effluent limitations established on the basis of *section 1311(b)(1)(C)* or *section 1313(d)* or *(e)* of this title, a permit may not be renewed, reissued, or modified to contain effluent limitations which are less stringent than the comparable effluent limitations in the previous permit except in compliance with *section 1313(d)(4)* [303(d)(4)] of this title." EPA explained that § 303(d)(4) will in most cases allow permitting authorities to issue permits reflecting new data, since (d)(4)(B) allows establishment of less stringent water quality-based effluent limits in a permit for discharge so long as the revised permit limit is consistent with a

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V. Implementation Procedures

The AISI also challenges several of the procedures that prescribe in detail the factors that a permitting authority must consider when assessing the merits of a permit application and the terms and conditions an authority must include in any permit that it [*994] may issue. We address each challenge in turn.

A. The Limits of Quantification

The EPA considers the discharge of certain toxic pollutants to be unacceptable even at levels where the presence of the pollutant cannot be measured accurately.

Procedure 8.A provides accordingly that "the permitting authority shall designate as the limit in the NPDES permit the [WQBEL] exactly as calculated."

The AISI argues that Procedures 8.A and 8.B, the latter of which details the analytical methods to be used when setting a permit limit, violate due process by mandating a standard that is too vague to warn industry of the scope of the conduct prohibited. A standard with which compliance cannot be assessed--and it is agreed that compliance with an effluent limitation set below the level of quantification simply cannot be assessed--is no standard at all for purposes of due process. For much the same reason, [**33] the AISI contends that the non-standards established by Procedures 8.A and 8.B are arbitrary and capricious and therefore unlawful under the Administrative Procedure Act. *5 U.S.C. § 706(1)(a)*

The EPA responds, first, that it has no choice in the [HN11] matter: the CWA requires the agency to set each effluent limitation at a level that will "protect the public health and welfare, enhance the quality of water and serve the purposes of the Act," *33 U.S.C. § 1313(c)(2)(A)*, and a pollutant may be so toxic that the discharge of even an immeasurably small amount would have a reasonable potential to endanger the public health and welfare. Nothing in the CWA suggests that the discharge of such a chemical should be treated State's antidegradation policy and "continues to assure compliance with applicable water quality standards." *58 Fed. Reg. at 20,837*. differently than the discharge of a chemical that is dangerous only at measurable levels. The EPA further contends that these Procedures raise no due process concern because, as matters now stand, there is no danger that an enforcement action will be taken based upon a measurement below the level of quantification. Procedure 8.B(3) provides that [**34] measurements are considered accurate only "down to the quantification level." The EPA has announced [HN12] that it "is the agency's policy that any effluent sample analyzed in accordance with the analytical method specified in the permit and other applicable procedures that is found to be below the quantification level shall be deemed in compliance with the WQBEL."

The AISI acknowledges that the Guidance provides that measurements are considered accurate only down to the level of quantification. Procedure 8.B(4) violates due process nonetheless, the AISI contends, because neither the States nor third parties are bound to follow the EPA in considering measurements below the level of quantification to be in compliance with the applicable effluent limitation. In fact, Procedure 8.B(4) explicitly provides that each State "permitting authority may specify in the permit the value to be used to interpret sample values below the quantification level."

We conclude that the AISI's challenge is both misdirected and unripe. It is misdirected because the petitioners have no grievance with the EPA. Under the regime created by the Guidance, a WQBEL set below the level of quantification, although technically [**35] enforceable, is without any genuine force unless and until a State should choose to attach a significant value to a measurement below the quantification level. The EPA cannot be said to have violated the due process rights of the petitioners simply by leaving the States free to work the alleged violation. Nor can the EPA itself be said to have acted arbitrarily and capriciously simply because the Guidance leaves the States with sufficient discretion to act in a way that would purportedly be arbitrary and capricious.

The challenge is unripe because no standard with which compliance would be difficult--much less impossible--to measure has yet been given any legal significance. If any state has even suggested that it intends to attach significance to measurements below the level of quantification, the AISI has not so informed the Court. Therefore, the arguments that the treatment afforded measurements below the quantification level is arbitrary and capricious and violates due process are not yet ripe for review.

[*995] B. Pollutant Minimization Program

Procedure 8.D provides that each permit will set out a pollutant minimization program (PMP) for each pollutant for which the permitting [**36] authority has imposed a WQBEL that is below the level of quantification. Each PMP must be designed to reduce the discharge of the regulated pollutant at the point source to a level that is at or below the WQBEL by monitoring and regulating the discharge of that pollutant from each source within the facility. The PMP will also require the implementation of "appropriate cost-effective control measures ... consistent with the control strategy." Procedure 8.D(4).

The AISI challenges Procedure 8.D on the ground that the CWA permits regulation only of point sources that discharge into the navigable waters of the United States and not of sources that discharge into a waste stream within a [HN13] facility. Section 301(a) of the CWA prohibits "the discharge of any pollutant" by any person. The "discharge of a pollutant" is defined as *"any addition* of any pollutant to *navigable waters* from any point source." (emphases added). In order to regulate such discharges, the Congress authorized the EPA in §§ 301 and 304 of the CWA to establish "effluent limitations," defined as restrictions placed upon pollutants "which are discharged from points sources into navigable waters." *33 U.S.C. §§ 1311* [**37] and *1314*. The AISI asserts that this statutory scheme authorizes the EPA to regulate pollutant discharge levels only at the point where a pipe leading from the facility discharges effluent into the navigable waters of the United States. By imposing restrictions upon pollutants that are discharged from internal plant sources into internal plant streams, the agency has, according to the petitioner, exceeded its clearly delimited statutory authority.

The EPA responds that the Act gives the agency broad powers to impose NPDES permit conditions in order "to assure compliance with" point source effluent limitations. *33 U.S.C. § 1342(a)(2)*. The EPA has equally broad authority under § 308 of the Act to impose monitoring and reporting requirements. These broad grants of authority, per the EPA, give the agency the power to require monitoring and control of internal sources, so long as those requirements further the goal of ensuring compliance at that point where effluent is ultimately discharged into the navigable waters of the United States.

We agree with the EPA that the CWA contemplates the imposition of monitoring and reporting requirements for internal plant sources. Section 401(a)(2) [**38] authorizes the Administrator to prescribe conditions for permits "including conditions on data and information collection to insure that the water quality standards are met." A permitting authority might be able to calculate an otherwise unquantifiable point source discharge level only by adding together the measurable levels of a pollutant contained in internal facility waste streams. For example, with respect to a pollutant for which the WQBEL is 10 ppm but the lowest measurable level is 40 ppm, determining that the pollutant is present in an internal waste stream at a concentration of 80 ppm and that this stream contributes a quarter of the total effluent ultimately discharged at the point source would inform the permitting authority that the pollutant is being discharged at the point source in a concentration of 20 ppm, i.e., at an impermissible level. It is reasonable to conclude, therefore, that § 401(a)(2) permits the monitoring of discharges from internal sources in order to calculate otherwise unquantifiable point source effluent levels.

The question whether the CWA contemplates an effluent limitation being imposed upon an internal source is not as easily resolved. Although [**39] we have held that the EPA may set a point source WQBEL at a level such that a plant would as a practical matter be forced to change internal equipment and processes in order to comply, *see American Paper Institute v. Train, 177 U.S. App. D.C. 181, 543 F.2d 328, 341 (D.C. Cir. 1976)*, we have not yet spoken to the question whether the EPA is authorized to require compliance with the WQBEL not only at the point source but also in

streams and pools that are inside the facility. We recur therefore to the text of the CWA.

[*996] The Act provides that when a permitting authority determines that "discharges of a pollutant from a point source ... would interfere with the attainment or maintenance of [applicable] water quality standards, ... effluent limitations (including alternative effluent control strategies) for such point source ... shall be established which can reasonably be expected to contribute to the attainment or maintenance of such water quality." *33 U.S.C. § 1312(a)*. The statute is clear: The EPA may regulate the pollutant levels in a waste stream that is discharged directly into the navigable waters of the United States through a "point source"; it is not authorized to regulate the pollutant levels [**40] in a facility's internal waste stream.

We are apprised of nothing in the policy underlying the CWA that undercuts the plain meaning of the statutory text. To the contrary, by authorizing the EPA to impose effluent limitations only at the point source, the Congress clearly intended to allow the permittee to choose its own control strategy. By imposing water quality based standards upon internal facility waste streams, the EPA seeks to deprive the individual permittee of the ability to choose between a control system that meets the point-source WQBEL by means of point source controls and a control system that meets the point source WQBEL by means of internal waste stream purification. As we have just seen, however, the statute does not permit this sort of meddling inside a facility.

We conclude, therefore, that although the EPA has the statutory authority to require the monitoring of discharges from sources within a facility, the agency exceeded its authority when it sought to impose effluent limitations upon non-point-source discharges. We therefore vacate Procedure 8.D insofar as it would impose the point-source WQBEL upon a facility's internal waste streams.

C. Mixing Zones [**41]

The AISI challenges Procedures 3.C, 3.D, and 3.E, which eliminate mixing zones for BCCs and establish required characteristics for all other mixing zones. A mixing zone is the area within a navigable water of the United States in which the discharge from a point source is initially diluted. Where a permitting authority has authorized a mixing zone, the permittee's compliance with the applicable water quality standards is assessed at the edge of the zone. A mixing zone is often extended by the permitting authority to include the area in which there occurs secondary mixing, i.e., mixing that is caused not by the turbulence created by the discharge itself but by naturally occurring currents and eddies.

Procedure 3.C phases out mixing zones for BCCs. Under the Procedure, no new mixing zones were to be granted for dischargers of BCCs after March 23, 1997. All existing mixing zones for discharges of BCCs were, moreover, to have been phased out by March 23, 2007. In the interim, existing mixing zones were also to have been brought into compliance with the more stringent requirements made applicable to mixing zones for substances other than BCCs by Procedures 3.D and 3.E. Those procedures [**42] limit the size of a mixing zone. Procedure 3.D provides that: "In no case shall a mixing zone be granted that exceeds the area where discharge-induced mixing occurs," and thus removes any area of secondary mixing from a mixing zone. Procedure 3.E requires that a mixing zone embrace an amount of water no more than 25 percent of the design flow of the receiving body of water. The AISI challenges all three Procedures.

1. Elimination of Mixing Zones For BCCs

The AISI asserts that the elimination of mixing zones for BCCs is arbitrary and capricious. Eliminating these mixing zones will not, according to the AISI, significantly reduce pollutant loadings to the Great Lakes. And the EPA, we are told, has conceded as much. See EPA, *Assessment of Compliance Costs Resulting from Implementation of the Final Great Lakes Water Quality Guidance,* Document

N6115L ("In terms of pollutant load reductions, the addition of mixing zones results in an insignificant decrease in pollutant load reductions").

Moreover, according to the petitioner, the elimination of BCC mixing zones would inflict upon industry costs that are excessive in relation to the degree of pollution reduction [*997] achieved, even [**43] if that reduction were not insignificant. For example, if BCC mixing zones are phased out, then the town of Owosso, Michigan will be forced to spend an additional $ 300,000 in order to remain in compliance with applicable water quality standards. The sole benefit derived from this expenditure would be the removal of 0.4 pounds of mercury per year from the town's municipal waste discharge. In view of the Owosso situation, the AISI asserts that the agency simply failed to consider the issue of cost--a serious problem raised in the comments--in formulating the final rule.

The EPA responds, first, that significant problems caused in the Great Lakes by the release of BCCs even in small amounts justify eliminating mixing zones for them. Even in a relatively open system, a BCC will persist in the ambient water and underlying sediment longer than will a run-of-the-mill pollutant. The Great Lakes, however, are a more-or-less closed system from which pollutants escape only over a long period of time. *See* Supplementary Information Document at 1 ("Lake Superior also has the longest retention time--the average time for one molecule of water to exit the system--of 173 years, while Lake Erie [**44] has the shortest at 2.7 years.") The retentive character of the Great Lakes combined with the persistent character of BCCs is what warrants, in the EPA's opinion, the elimination of BCC mixing zones. The EPA also observes that the characterization of BCC loading reductions as "insignificant" was made by the agency's economists; the technical and policy staffs, who were aware of the environmental peculiarities of the Great Lakes, characterized those same reductions as significant.

The EPA also maintains that it responded to concerns about the unreasonable cost of eliminating some BCC mixing zones by providing that such mixing zones be allowed in special circumstances. [HN14] A permitting authority may permit a BCC mixing zone provided that it first finds that:

> The discharger is in compliance with and will continue to implement all applicable technology-based treatment and pretreatment requirements of CWA sections 301, 302, 304, 306, 307, 402, and is in compliance with its existing NPDES water quality-based effluent limitations, including those based on a mixing zone; and the discharger has reduced and will continue to reduce the loading of the BCC for which a mixing zone is requested [**45] to the maximum extent possible.

Procedure 3.C(6)(a)(i)-(ii).

Although the EPA appears adequately to have explained the environmental justification for its decision, we are unable to accept, based upon the record before us, the EPA's claim to have considered the ratio of cost to benefit. The agency estimated the total cost of eliminating BCC mixing zones at $ 200,000. The agency failed to explain--indeed even to acknowledge--the comment estimating at approximately $ 300,000 the cost to one town of removing mercury from its sewage discharge. If Owosso were the only contributor of pollutants to the Great Lakes, this disparity would be troubling. In light of the number of municipal and industrial point sources in the Great Lakes Basin, however, the EPA appears to have adopted a cost estimate that can only be described as fanciful.

We therefore grant the petition insofar as it challenges Procedure 3.C. Alt-

hough the EPA appears to have shown that eliminating mixing zones is not without some environmental benefit, the agency simply failed to address whether the measure is cost-justified. We remand the matter in order to afford the EPA an opportunity to do just that.

2. [**46] Limitations on Other Mixing Zones.

The AISI also challenges the requirement of Procedure 3.E that a mixing zone encompass no more than 25 percent of the design flow of the receiving water. The AISI observes that the EPA purportedly relied upon a 1968 recommendation of the National Technical Advisory Committee that "mixing zones in streams should be limited to twenty five percent of the cross sectional area of the river to allow a free zone of passage for aquatic organisms." The agency's reliance is misplaced, the AISI contends, because 25 percent of the "cross-sectional area" of a stream--the measure recommended by the [*998] Advisory Committee--is not the same as 25 percent of the "design flow" of that stream--the measure adopted by the EPA.

We conclude that the EPA adequately justified its decision to establish uniform default dimensions for mixing zones. The EPA concluded in the Supplementary Information Document that "the value of 25 percent of total river flow is a rational estimate of the amount of the river flow in 25 percent of the cross-sectional area," and it is more easily measured. Any concern that the substitute criterion will produce poorly proportioned mixing zones should [**47] be allayed by the fact that a permittee may demonstrate that "an alternative dilution fraction is appropriate."*Id.* Therefore, in a river where 25 percent of river flow does not correspond even roughly to 25 percent of cross sectional area, the permitting authority may adjust the mixing zone accordingly.

The AISI also challenges Procedure 3.D insofar as it limits mixing zones to the discharge-induced mixing area, "which is the area in the immediate vicinity of the discharge where mixing occurs due to the turbulence created by the momentum of the discharge." The EPA defines this area, for practical purposes, as one embracing a quantity of water equal to ten times the quantity of effluent. The AISI contends that this approach represents an unjustified departure from past EPA practice.

The EPA responds that it adopted the 10:1 rule only after reviewing studies conducted for the Milwaukee South Shore and for the Green Bay Metropolitan wastewater treatment plants. These studies concluded that it was reasonable to limit mixing zones to an area that allows 10 parts receiving water for each part of effluent because such a zone generally corresponds to the area "where the velocity and [**48] momentum associated with an effluent being discharged from the end of a pipe was dissipated." SID at 274. The EPA recognized that other processes would, over time, further dilute the pollutant and that site specific conditions might render the 10:1 ratio inappropriate. The EPA concluded, however, that "these [two] studies provide a scientific basis for default mixing zone assumptions for discharges to open waters of the Great Lakes." *Id.*

Again we find that the EPA has reasonably decided to rely upon conservative but adequately supportive science. The two referenced studies reveal that most mixing occurs in the area covered by the 10:1 rule. The EPA recognized that additional mixing may occur outside of this area. As a default rule, however, the EPA settled upon that area in which, as the available data revealed, discharge-induced mixing normally occurs. Once again the EPA provided for a party to show that these assumptions are inappropriate in a particular situation: "The final Guidance does allow for recognition of site specific conditions by allowing alternative mixing zones subject to the mixing zone demonstration requirements" of Procedure 3.F. We find nothing arbitrary [**49] or capricious in this decision. We therefore deny the petition insofar as it challenges Procedures 3.D and 3.E.

D. Intake Pollutants

The EPA considers any discharge of a pollutant into the navigable waters of

the United States, including the return of a pollutant to the body of water from which it was drawn, to be an "addition" of that pollutant to that body of water within the meaning of the Clean Water Act. Accordingly, the EPA did not require that a permitting authority make any allowance for these so-called intake pollutants. A facility must as a result obtain a permit even if its only discharge is the return of an intake pollutant into the river or stream from which it was taken.

The AISI challenges the provisions applicable to intake pollutants on three grounds. First, the AISI asserts that the CWA does not authorize the agency to hold a point source responsible for the intake pollutants it discharges. Second, the AISI contends that to hold a point source responsible for intake pollutants violates the due process rights of the discharger by holding it responsible for pollutants it did not originally add to the water. Finally, the AISI alleges that various aspects of [**50] Procedures 5.D and 5.E are arbitrary and capricious.

[*999] Before responding to these allegations, the EPA asserts that they are all unripe for review. Whether the discharge of an intake pollutant constitutes an "addition" for purposes of the CWA is, the EPA contends, a question that cannot be answered in the abstract. The court must consider a variety of factors, including: how a facility uses intake water; whether and how the intake water is removed from waters of the United States; the quality of the receiving water; the quality of the water discharged; and whether the intake water originates and is discharged into the same body of water. The EPA urges that we therefore postpone ruling on this issue until we have a well-developed and concrete factual situation before us.

The AISI maintains that its challenge is ripe for review because it implicates the EPA's purely legal interpretation of the CWA. The EPA has interpreted an "addition" to include all intake pollutants passing through a discharge pipe. The AISI contends that this interpretation can be adjudged erroneous quite apart from any factual considerations.

We agree with the EPA that these challenges are not yet ripe for review. [**51] This Circuit has twice held that similar intake pollutant provisions remained unripe for review until they were implemented in a particular factual setting. See *NRDC v. EPA, 859 F.2d 156, 204-205 (D.C. Cir. 1988)*; *Diamond Shamrock Corp. v. Costle, 188 U.S. App. D.C. 407, 580 F.2d 670, 674 (D.C. Cir. 1978)*. We are concerned in the present case, as we were in *NRDC v. EPA,* that "the broad legal issue [of what constitutes an "addition" under the CWA] may have links to the concededly fact-dependent ones that we cannot now fully perceive." *859 F.2d at 205*. For example, Procedures 5.D and 5.E provide for intake credits and offsets in certain situations; this Court would need to know how those provisions operate in practice in order to address the petitioner's claim that the EPA has acted in a way that is arbitrary and capricious or violates the petitioner's due process rights. We concede, as we did in *NRDC v. EPA,* that the question of statutory interpretation "appears purely legal in character" and that we "might well carve this issue out from the more fact-bound claims and find it ripe." *Id.* As in *NRDC,* however, we continue to think that the legal challenge is bound up in the more fact-dependent [**52] claims "enough to tilt the balance in favor of finding not only the fact-dependent claims, but also the more purely legal one, unripe." *Id.*

E. Reasonable Potential Procedures[HN15]

An NPDES permit must contain a WQBEL for any discharge that either will cause or has the reasonable potential to cause or to contribute to an excursion above a water quality standard. See *40 C.F.R. § 122.44(d)(1)*. Under EPA regulations, a permitting authority "must use all relevant available data, including facility-specific effluent monitoring data where available" and employ "procedures which account for existing controls on point and non-point sources of pollution, the variability of the pollutant or pollutant parameter in the effluent, the sensitivity of the species to toxicity testing ... and, where appropriate, the dilution of the effluent in

the receiving water" when it determines whether a pollutant discharge has the reasonable potential to cause an excursion above a water quality standard. Id. at *§ 122.44(d)(1)(ii)*.

The Guidance establishes a new two-step procedure for determining whether there is a reasonable potential for a given discharge to cause an exceedance of a water quality standard. [**53] The permitting authority must, first, set a preliminary effluent limitation (PEL) for each point source. Each PEL is calculated so that a discharge below the PEL level would not have a reasonable potential to cause an exceedance. Second, the permitting authority must determine the projected effluent quality (PEQ) of the discharge. The PEQ is set at "the 95 percent confidence level of the 95th percentile based on a log-normal distribution of the effluent concentration; or the maximum observed effluent concentration, whichever is greater." Procedure 5.B(1). Whenever the PEQ of a particular point source exceeds the PEL for that point source, the permitting authority must set a WQBEL for each pollutant that is the cause of such an exceedance.

[*1000] The AISI first complains that this new procedure, by providing that a PEQ must be no lower than the "maximum observed effluent concentration," will allow a permitting au- thority to base a "reasonable potential" finding upon only one effluent quality measurement. By contrast, under the national program, a permitting authority must always consider the variability of the pollutant in the effluent and, therefore, must always take into account effluent [**54] quality measurements that will reveal the variability of the concentration of the pollutant.

The EPA responds that, although the Guidance does allow for regulation to be based upon only one measurement of a discharge, the procedures are nevertheless consistent with the national program because the permitting authority must, under the Guidance, conclude that the measurement before it is "valid and representative" before it may base any PEQ determination upon that one measurement. *See* SID at 317 ("Permittees should ensure they are reporting valid, representative data. See *40 C.F.R. § 122.41(j)(1)*. Where the permittee believes a certain effluent measurement to not be representative of the effluent, the permittee should bring this to the permitting authority's attention.") The EPA also observes that the permittee is in the best position to remedy any perceived inadequacy in the data set presented to the permitting authority.

The EPA adequately responded to the AISI's concern by effectively mandating that a PEQ must not be based upon a single data set unless the permitting authority first concludes that the measurements in that set are "valid and representative" for the point source. [**55] In order to be "valid and representative," the single data set must account for the variability of the pollutant in the effluent. The EPA concedes that a single data set will not often meet this standard. When one set does suffice, however, it will be one that accounts for the variability with which the AISI is concerned.

The AISI next complains about Procedure 5.F, which provides that if a pollutant is present in unacceptable levels in fish tissue, then any facility that discharges "detectable levels" of that pollutant will be deemed to have a reasonable potential to cause an exceedance of a water quality standard. It is arbitrary and capricious, the AISI maintains, to conclude based upon the exceedance of a certain level in fish tissue that every plant emitting any amount of the suspect pollutant into a body of water has the reasonable potential to contribute to that exceedance in that body of water.

The EPA recognized that the presence of a pollutant in both fish tissue and an effluent stream is not "necessarily an indication that discharges of the effluent is solely the cause of the fish contamination, or even a substantial contributor of such contamination." The EPA nevertheless [**56] concluded that the presence of a pollutant in fish tissue and in an effluent is an "indication that the discharge of the effluent is a possible contributor of such contamination and therefore exhibits the reasonable potential to cause or contribute to the excursion above an applica-

ble water quality standard." SID at 334-35. In other words, if the fish-tissue standard for a pollutant is not being met, then any source discharging that pollutant may be presumed to have a reasonable potential to contribute to that standard not being met.

We agree with the EPA that it is not arbitrary and capricious to presume that a source that contributes a pollutant to a body of water in which the standard for that pollutant has been exceeded has the reasonable potential to contribute to that exceedance. The AISI seems to be under the impression that, in order to establish that a discharge has a reasonable potential to cause an exceedance, a permitting authority must demonstrate a precise causal connection between that particular discharge and the relevant exceedance. This is not the case. As the term "reasonable potential" suggests, there need only be a reasonable possibility that any particular discharge [**57] of the pollutant is contributing to the exceedance.

Finally, the AISI asserts that requiring that the PEQ be set "at the upper bound of a 95% confidence interval at the 95th percentile of expected effluent concentration" results in an unreasonably compounded safety factor. According to the [*1001] AISI, the agency's decision to base the PEQ upon the 95th percentile of the most conservative 5% of the projected effluents simply cannot be reconciled with the more lenient methods employed in the national NPDES program.

Contrary to the assertions of the AISI, the EPA's decision to rely upon worst case assumptions does not represent a departure, much less a radical and unexplained departure, from past agency practice. As the Supplementary Information Document for this rulemaking made clear, the agency has "always meant the reasonable potential statistical analysis [employed in the national program] to be worst case." SID at 322. That assertion is supported by the EPA's 1991 Technical Support Document for Water Quality Based Toxics Control, in which the agency identified 'the 95th percentile upper bound estimate of effluent data [as] an acceptable upper bound for purposes of making reasonable [**58] worst case estimates of effluent quality." We can see no merit, therefore, in the AISI's contention that the EPA has inexplicably departed from its past practices. Hence we deny the petition insofar as it challenges the reasonable potential procedures contained in Procedure 5.

VI. Consistency with the Great Lakes Water Quality Agreement

Section 118(c)(2) requires EPA to issue "guidance" that "shall conform with the objectives and provisions of the Great Lakes Water Quality Agreement." NWF argues that the Guidance EPA promulgated violates this provision, and is thus arbitrary and capricious, for three reasons: (1) EPA failed to explain adequately how the Guidance achieves virtual elimination and zero discharge of persistent toxic substances; (2) the Guidance does not conform with the portion of the Agreement relating to this subject because the Guidance contains exceptions to the "mixing zone" phaseout for the BCCs; and (3) the Guidance fails to provide implementation procedures for controlling "nonpoint" or diffuse sources of pollution. NWF Brief at 12-13. None of NWF's arguments are well-taken.

The Guidance did not have to explain how it would achieve virtual elimination and [**59] zero discharge because the Agreement treats these merely as goals, not mandates. Article II of the Agreement, entitled "Purpose," states that "the Parties agree ... to eliminate or reduce to the maximum amount practicable the discharge of pollutants into the Great Lakes System," and that the "policy" of the parties is zero discharge and virtual elimination. Section 118 follows the same approach. It states that "the United States should seek to attain the *goals* embodied in the Great Lakes Water Quality Agreement of 1978 ... with particular emphasis on *goals* related to toxic pollutants." § 118(a)(1)(B) (emphasis added). Neither the Agreement nor § 118 contains language stating that total elimination must be achieved at any cost.

The Guidance's mixing zone provisions also conform with the Agreement.

The Agreement states: "Pending the achievement of the virtual elimination of persistent toxic substances, the size of such [mixing] zones shall be reduced to the maximum extent possible by the best available technology so as to limit the effects of toxic substances in the vicinity of these discharges." Agreement, Annex 2, P 2(d). The Guidance prohibits mixing zones for new and [**60] expanding discharges of BCCs in the Great Lakes and prohibits mixing zones for all other existing BCC discharges after 12 years in almost all circumstances. Procedure 3; SID at 268. There is an exception for existing discharges after 2007. But the exception applies only if the discharger is in compliance with all applicable treatment and pretreatment requirements of the Act; demonstrates that it is reducing its BCC discharges to its maximum capability, taking into account technical and economic limitations; and still cannot meet the applicable effluent limitation in the absence of a mixing zone. *See id.*; SID at 269. The exception is narrower still because the discharger must also conduct a pollutant minimization program (if required by the Guidance under Procedure 8.D), and demonstrate that alternative means for reducing BCCs elsewhere in the watershed have been evaluated. Procedure 3.C(6)(c)(vii)-(viii). Furthermore, the exception is limited to one permit term, and may not be granted thereafter " [*1002] unless the State or Tribe makes the necessary findings discussed above for each successive permit application in which a mixing zone for BCCs is sought." Procedure 3.C(6)(c)(iii).

There [**61] is no inconsistency between this exception and the Agreement. EPA recognized that "in certain limited circumstances, the elimination of mixing zones for BCCs for existing discharges" may be "infeasible," while the Agreement required reductions to "maximum extent possible." SID at 269. If there is a material difference between these formulations, it eludes us. *See National Wildlife Fed'n v. Gorsuch, 224 U.S. App. D.C. 41, 693 F.2d 156, 181 (D.C. Cir. 1982).*

As to the Guidance's approach to nonpoint source pollution, this too is consistent with both § 118 and the Agreement. Pollutants enter the Great Lakes from various nonpoint sources, including industrial and municipal emissions to the air, urban and agricultural run-off, resuspension of pollutants from contaminated sediments, Superfund sites, and spills. *See* SID at 16. The Agreement recognizes this problem, and in Annex 13, entitled "Pollution From Non-Point Sources," it calls upon the parties to develop measures which "shall include provisions for regulation of non-point sources of pollution." Annex 14, entitled "Contaminated Sediment," states under the heading "Long-Term Measures," "the Parties, in cooperation with State and Provincial Governments, [**62] shall also ensure that measures are adopted for the management of contaminated sediment...." Annex 15 ("Airborne Toxic Substances") calls upon the parties "to implement pollution control measures for the purpose of reducing atmospheric deposition of toxic substances...." "Measures," "management," "reducing," "regulation"--these, of course, are generalities. The Guidance is more specific. EPA's water quality criteria and antidegradation provisions apply to the entire Great Lakes System, whether the pollution enters the waters from point or nonpoint sources. *See 40 C.F.R. § 132.4.* The Guidance's Total Maximum Daily Load (TMDL) provisions allow "permitting authorities to consider the presence ... of nonpoint source(s) ... in establishing [controls]." SID at 17. The Guidance directs that the Great Lakes States "shall adopt provisions ... for the purpose of developing Total Maximum Daily Loads." Procedure 3. A TMDL "sets and allocates the maximum amount of a pollutant that may be introduced into a water body and still assure attainment and maintenance of water quality standards." *40 C.F.R. § 132.2.* The Guidance explains that "the TMDL quantifies the maximum allowable loading of [**63] a pollutant to a water body and allocates the loading capacity to contributing point and nonpoint sources (including natural background) such that water quality standards for that pollutant will be attained." *60*

Fed. Reg. at 15,376. Procedure 3.B(3)(a) states that "TMDLs shall include [waste-load allocations] for point sources and load allocations for nonpoint sources, including natural background," and (b) states that nonpoint source load allocations shall be based on existing pollutant loadings if changes are not reasonably anticipated to occur, or increases in loadings if changes are expected to occur.

The Guidance, in other words, contains regulations and measures for managing and reducing pollution from nonpoint sources. It therefore conforms to the Agreement. More need not be said on the subject.

VII. Endangered Species Act

The Guidance requires States to include provisions in their programs to ensure that water quality adequately protects endangered and threatened species. Specifically, [HN16] *40 C.F.R. § 132.5(h)* states,

> A submission by a Great Lakes State or Tribe will need to include any provisions that EPA determines, based on EPA's authorities under the [**64] Clean Water Act and the results of consultation under section 7 of the Endangered Species Act, are necessary to ensure that water quality is not likely to jeopardize the continued existence of any endangered or threatened species listed under section 4 of the Endangered Species Act or result in the destruction or adverse modification of such species' critical habitat.

See also SID at 88-91. The Guidance also states that neither a variance to a water quality standard for point sources nor a mixing [*1003] zone will be granted if either would jeopardize the continued existence of any endangered or threatened species or adversely impact its habitat, Procedures 2.A(2), 3.C(6)(c)(ii), 3.D(4), 3.E(4)(c), 3.E(5), 3.F(1)(e). It also requires States to adopt more stringent site-specific criteria necessary to ensure that water quality is not likely to jeopardize the continued existence of species listed or proposed for listing under the ESA. Procedures 1.A, 1.A(1)(d), 1.A(2)(c). As indicated by *§ 132.5(h)*, EPA consulted with the United States Fish and Wildlife Service (FWS), pursuant to § 7(a)(2) of the Endangered Species Act (ESA), *16 U.S.C. § 1536(a)(2)*, regarding the Guidance. [**65] *See 60 Fed. Reg. at 15,384.* Section 7(a) of the ESA provides that each agency shall, in consultation with FWS, "insure that any action authorized, funded, or carried out by such agency ... is not likely to jeopardize the continued existence of any endangered species or threatened species...." Under FWS's regulations, agency "action" includes "the promulgation of regulations" and "actions directly or indirectly causing modifications to ... water." 50 C.F.R. § 402.2.

AISI challenges the Guidance's endangered species provisions on the ground that EPA has no authority to require State program elements to protect endangered species. As AISI sees it, the ESA imposed no obligations on EPA either in the issuance of the Guidance or in the approval of water quality programs of the Great Lakes States, because two preconditions specified in the ESA were missing: (1) there is no federal agency "action" under ESA § 7(a)(2), *16 U.S.C. § 1536(a)(2)*, and *(2)* there is no jeopardy to endangered species or their habitat.

We uphold this portion of the Guidance, but not because of the ESA. Section 118(c)(2) provides that the Guidance "shall specify numerical limits on pollutants in ambient Great [**66] Lakes waters to protect human health, *aquatic life, and wildlife,* and shall provide guidance to the Great Lakes States on minimum water quality standards ...." (emphasis added) This is all the authority the EPA needed to promulgate regulations designed to protect endangered, threatened and other species in the Great Lakes System. As EPA said,

> the prevention of water quality conditions that would be likely to jeopardize the continued existence of any species is inherent in the CWA's requirement for EPA to provide guidance on minimum water quality standards to protect aquatic life and wildlife in the Great Lakes Basin (CWA section 118(c)(2)) ... Obviously, if impaired water quality will likely cause the extinction of a species, such water quality would not meet the Act's requirements.

SID at 86.

VIII. Pollutant Specific Criteria

Section 118(c)(2)(A) directs the agency to "specify numerical limits on pollutants" and "provide guidance on ... minimum water quality standards." The agency accordingly established numeric ambient water quality criteria for many specific pollutants. *40 C.F.R. § 132.6*. The agency derived criteria in four categories: acute and chronic [**67] criteria for the protection of aquatic life, chronic criteria for the protection of human health, and chronic criteria for the protection of wildlife.

Petitioners challenge as arbitrary and capricious the human health and wildlife criteria for mercury and for PCBs. [7] We consider these challenges in turn.

> 7 In their initial brief, petitioners also challenged the agency's acute criterion for the protection of aquatic life from total selenium. The agency has since moved to remand that criterion. The issue is no longer part of this appeal. exposure to mercury considered permissible) for humans that it knew to be too low. We reject each of these challenges and uphold the mercury criteria.

A. Mercury Criteria

Petitioners contend that the Guidance's human health and wildlife criteria for mercury are arbitrary and capricious. They make three specific challenges. They argue that the agency (1) used a flawed methodology to determine the BAF for mercury, (2) relied on a methylmercury bioconcentration factor (BCF) [**68] that did not satisfy its own definition of acceptable data, and (3) employed a reference dose (the level of exposure to mecury considered permissible) for humans that it [*1004] knew to be too low. We reject each of these challenges and uphold th emercury criteria.

1. Methodology for Determining Mercury Bioaccumulation Factor The criteria petitioners challenge are designed to protect humans and wildlife from exposure to mercury. In order to accomplish this goal the criteria must account for the ingestion of mercury both from eating fish and from drinking water.

In determining how much mercury humans and wildlife are exposed to from eating fish, the agency must account for bioaccumulation. Bioaccumulation is the process by which a substance becomes concentrated in fish tissue through exposure to the substance in water, food, and sediment. Because of bioaccumulation, certain chemicals appear in much higher concentrations in the tissue of organisms at upper levels of the food chain than in organisms at lower levels. For these chemicals, failure to account for bioaccumulation could result in underestimation of the amount that humans and wildlife ingest.

In the Guidance, the agency accounted for bioaccumulation through the use of BAFs. The agency defines a BAF as "the ratio (in L/kg) of a substance's concentration in tissue of an aquatic organism [**69] to its concentration in the ambient water, in situations where both the organism and its food are exposed and the ratio does not change substantially over time." *40 C.F.R. § 132.2*. The higher the BAF the greater is the chemical's tendency to bioaccumulate. The greater the tendency to bioaccumulate the stricter the criteria must be to protect humans and wildlife.

The agency's preferred method for calculating a BAF is a field study of fish collected in the Great Lakes. For mercury, however, no acceptable field study was available. The agency needed to generate a mercury BAF. It did so by multiplying a laboratory-measured "bioconcentration factor" by a "foodchain multiplier." The bioconcentration factor is a measure of the net uptake of mercury from water through gills and skin (not through ingestion). The food-chain multiplier accounts for the increased concentration of mercury as it makes its way through the food chain. The resulting BAF was used to calculate the mercury criteria that was applied across the Great Lakes.

Petitioners argue that this method for generating the mercury BAF was arbitrary and capricious. Their overarching argument is that the agency's method is inconsistent [**70] with reality. The agency acknowledges that it acted on the basis of less than perfect information but contends that the method it chose was reasonable and lawful.

We begin by noting that this case presented the agency with a classic and difficult choice. Possessing imperfect scientific information, it had to decide whether to proceed on that basis or to invest the resources to conduct the perfect study. It chose to do the former. This is the type of decision to which this court will generally apply the deferential standard of *5 U.S.C. § 706(2)(A)*. *See, e.g., Chemical Mfrs. Ass'n v. EPA, 307 U.S. App. D.C. 392, 28 F.3d 1259, 1265 (D.C. Cir. 1994)*; *Small Refiner Lead Phase-Down Task Force v. US EPA, 227 U.S. App. D.C. 201, 705 F.2d 506, 535 (D.C. Cir. 1983)*. [HN17] Our deference, however, is not without limits. The agency's choice will be reversed as arbitrary and capricious if there is "simply no rational relationship" between the model chosen and the situation to which it is applied. *Chemical Mfrs. Ass'n, 28 F.3d at 1265*; *see also Eagle-Picher Indus., Inc. v. US EPA, 759 F.2d 905, 921 (D.C. Cir. 1985)* (agency must provide a full analytic defense when its model is challenged).

Petitioners contend that there are two reasons [**71] why the agency's method fails to satisfy this minimal standard. They claim first that the agency did not account for the wide variations in mercury concentrations that occur in nature. The agency disputes this. It contends that it accounted for mercury's variability in two ways. First, it relied on systemwide field tests to establish the bioconcentration factor and food chain multiplier that it used to compute the BAF.

Respondent's Brief at 90-91. Second, it allowed for site-specific modifications.

The agency's model may, as petitioners suggest, be somewhat simplistic. It may at some level make assumptions that are not perfectly consistent with natural conditions. This does not mean, however, that use of the [*1005] model is arbitrary. *See, e.g., Chemical Mfrs. Ass'n, 28 F.3d at 1264-65*. [HN18] We will hold that the agency's use of the model is arbitrary only if we conclude that the model bears "*no* rational relationship" to the reality it purports to represent. *Id. at 1265* (emphasis added). Petitioners have not convinced us that this is so. They claim that the agency did not account for variability in mercury concentrations, but they are wrong. The agency incorporated local data [**72] into its determination of the mercury BAF. In addition, the Guidance allows permitting authorities to modify mercury BAFs to account for local conditions. Procedure 1.A(3). Given the applicable standard of review, we hold that the Guidance's scheme is an acceptable means of allowing for local variation while also accomplishing the statute's goal of establishing "minimum water quality standards ... for the Great Lakes System." § 118(c)(2)(A).

Petitioners' second claim is that the agency's model is flawed because it does not account for the ingestion of mercury from sediments. Sediments are a major source of mercury for many fish. Comparing tissue concentrations to water concentrations alone, argue petitioners, therefore leads to a BAF that is too high. The agency disagrees that this is a flaw in its method. It claims that mercury concentrations in water, sediment, and tissue are all interrelated. Given that mercury circulates through these three media, the

concentration level in water includes contributions of mercury from sediment. It was therefore appropriate for the agency to compare the concentration in fish tissue to the concentration in water.

This second challenge is similar [**73] to the first. Petitioners have identified what they claim is a flaw in the agency's model. The existence of a flaw, however, does not require us to hold that the agency's use of the model was arbitrary. We will reach this conclusion only if there is no rational relationship between the model chosen and the situation to which it is applied. *See, e.g., Chemical Mfrs. Ass'n, 28 F.3d at 1265.*

In this case there is a rational relationship. The agency has provided a rational response to petitioners' criticisms. It claims that mercury behaves in such a fashion that it need not directly account for ingestion from sediment. Petitioners do not dispute that mercury behaves as the agency suggests it does. They merely contend that the agency's model does not account for all the ways in which fish ingest mercury from sediments and that the agency's method is therefore a "poor means of predicting mercury bioaccumulation." Petitioners have not demonstrated to us that the agency's explanation is irrational. We therefore reject their contention that use of the model was arbitrary.

In addition to their general challenge to the agency's methodology for determining the mercury BAF, petitioners also [**74] contend that the agency failed to respond to comments that suggested alternatives. They point particularly to the agency's failure to consider the use of a "bioavailability index" or a "dynamic model." This challenge also fails. "[HN19] The failure to respond to comments is significant only insofar as it demonstrates that the agency's decision was not based on a consideration of the relevant factors." *Thompson v. Clark, 239 U.S. App. D.C. 179, 741 F.2d 401, 409 (D.C. Cir. 1984)* (internal quotations and citations omitted); *see also NRDC, 859 F.2d at 188* ("The fundamental purpose of the response requirement is, of course, to show that the agency has indeed considered all significant points articulated by the public."). In this case, the record demonstrates that the agency considered the "relevant factors" raised by the suggested alternatives. The agency explained why it did not use a bioavailability index. *See* Excerpts from the EPA Response to Comments Document No. I.63500. The agency did not explicitly explain why it did not accept the "dynamic model." In its explanation of the mercury BAF in the Supplementary Information Document, however, the agency wrote that "sequestration of an inorganic chemical [**75] in sediment is generally not important because BAFs are derived based on the relationship between fish tissue concentrations and the water column." This comment demonstrates that the agency at least considered whether it should adopt a model that more directly accounted for the complex cycling of mercury between water, sediment, and fish tissue. [*1006] This is all that the response to comment requirement demands.

2. The Methylmercury Bioconcentration Factor

The agency derived the mercury BAF by multiplying a laboratory-measured BCF by a food-chain multiplier. As explained above, a BCF is a measure of an aquatic organism's net uptake of a pollutant from water alone. The BCF the agency used in its calculation was a weighted average of the BCFs for methylmercury and inorganic mercury. The methylmercury BCF the agency used was partially based on a study (the "Olson study") that petitioners now contend is flawed. They argue that the fish in the Olson study were exposed to mercury from both sediments and from food, and that the study therefore should not have been used to determine the BCF, which is a measure of intake from water alone.

The agency acknowledged that the fish in the Olson [**76] study were "grazers" that may have been exposed to mercury from the ingestion of contaminated food. It explained in response to a comment, however, that this was unlikely to have affected the results of the Olson study because "the food that is added is unlikely to sorb a substantial amount of mercury before it is eaten."

We begin our analysis by noting that this is a question of scientific judgment. The petitioners claim that the study is methodologically flawed; the agency responds that it is not. On such questions a reviewing court must be "at its most deferential." *Baltimore Gas & Elec. Co. v. NRDC, 462 U.S. 87, 103, 76 L. Ed. 2d 437, 103 S. Ct. 2246 (1983)* ("[HN20] When examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential."); *American Legion v. Derwinski, 311 U.S. App. D.C. 385, 54 F.3d 789, 795 (D.C. Cir. 1995)* ("Given the nature of the scientific expertise brought to bear on the issue of whether to continue the Center's Agent Orange Study, the court's review is at its most deferential."), *cert. denied, 133 L. Ed. 2d 655, 116 S. Ct. 697 (1996)*; *Safe Buildings Alliance v. EPA, 269 U.S. App. D.C. 366, 846 F.2d 79, 83* (D.C. Cir.) ("In view of the special deference owed to an [**77] agency's expert judgment on matters at the frontiers of science...."), *cert. denied, 488 U.S. 942, 102 L. Ed. 2d 355, 109 S. Ct. 366 (1988)*.

Given this standard of review, it is clear that petitioners' challenge cannot succeed. During this rulemaking, the agency considered the very criticism that petitioners now raise before this court. It gave a rational explanation for why it used the study despite its supposed flaw. Nothing more is required.

3. The Acceptable Daily Exposure (ADE) Value

Petitioners' next challenge is to the ADE the agency used in calculating the human health criterion for mercury. An ADE (a/k/a "reference dose" or "RfD") is an estimate of the level of daily exposure to a chemical that is harmless to humans. ADEs are used in calculating human health criteria. The lower the ADE that is chosen, the stricter the human health criteria that is generated.

In this rulemaking, the agency used an ADE for mercury of .06 ug/kg/d. Sometime shortly before the issuance of the Guidance, however, the agency's "RfD Work Group" announced that the appropriate ADE for mercury was .1, not .06. The agency acknowledged in the Guidance that the ADE had changed, but still calculated the human health criterion for [**78] mercury using the old, lower ADE. The agency explained that, given that it was under a court order to publish the Guidance by a certain date, there was not enough time to publish the new ADE, receive comments, and then revise. The result was that the human health criterion for mercury was stricter than it would have been had the agency used the revised figure. The agency has since issued a separate guidance alerting regional offices and states that where an ADE has been revised, the agency will approve criteria using the revised ADE. Questions and Answers on Implementing the Great Lakes Guidance: Set 2 at 3.

Petitioners claim that the mercury criterion for humans is arbitrary because it was based on an ADE the agency knew to be inaccurate. The agency argues that the question is moot, and in the alternative, that [*1007] its reliance on the outdated ADE was reasonable.

As for mootness, the agency is wrong. In *United States v. W.T. Grant Co., 345 U.S. 629, 632, 73 S. Ct. 894, 97 L. Ed. 1303 (1953)*, the Court stated that "[HN21] voluntary cessation of allegedly illegal conduct does not deprive the tribunal of power to hear and determine the case, *i.e.*, does not make the case moot." The Court noted an exception to this [**79] general rule for cases in which the defendant could meet the "heavy" burden of proving that the wrong will not be repeated. *Id. at 633*. In this case this heavy burden has not been met. There are numerous ways whereby the mercury criterion based on the inaccurate ADE could be enforced. The agency's subsequent statement could be withdrawn, it could be stricken down by a reviewing court, or it could be ignored by local EPA officials.

As for the merits, however, the agency is correct. The agency did not act arbitrarily in sticking to the old ADE. *ICC v. City of Jersey City, 322 U.S. 503, 64 S. Ct. 1129, 88 L. Ed. 1420 (1944)*, makes this clear. In *Jersey City* the Court was presented with the argument that an

ICC order could not become final until the Commission had granted a full rehearing. In rejecting the argument, the Court wrote:

> Administrative consideration of evidence ... always creates a gap between the time the record is closed and the time the administrative decision is promulgated.... If upon the coming down of the order litigants might demand rehearings as a matter of law because some new circumstance has arisen, some new trend has been observed, or some new fact discovered, there [**80] would be little hope that the administrative process could ever be consummated in an order that would not be subject to reopening.

Id. at 514; *see also Vermont Yankee Nuclear Power Corp. v. NRDC, 435 U.S. 519, 554-55, 55 L. Ed. 2d 460, 98 S. Ct. 1197 (1978)*; *Group Against Smog & Pollution, Inc. v. US EPA, 214 U.S. App. D.C. 466, 665 F.2d 1284, 1291-92 (D.C. Cir. 1981)*.

This principle applies with full force in this case. The agency was not obliged to stop the entire process because a new piece of evidence emerged. If this were true then the administrative process could never be completed. An agency does, however, have an obligation to deal with newly acquired evidence in some reasonable fashion. In this case the agency met this minimal requirement. It mentioned the new evidence in the Guidance itself and subsequently announced that states could base their mercury human health criterion on the revised figure. Nothing more is required.

We therefore reject each of the petitioners' challenges to the criteria for mercury. As we do so we add an observation. Cases such as this require the court to evaluate an agency's use of complex scientific evidence. In such cases the parties should ensure that enough background explanation [**81] is provided so that non-specialists can understand the significance of the points that are made. To paraphrase Holmes, a page of background discussion is sometimes worth a volume of detailed analysis. *New York Trust Co. v. Eisner, 256 U.S. 345, 349, 65 L. Ed. 963, 41 S. Ct. 506 (1921)* (Holmes, J.) ("Upon this point a page of history is worth a volume of logic.").

B. The PCB Criteria

Petitioners raise three challenges to the Guidance's human health and wildlife criteria for PCBs. Their first argument is that the agency made mathematical errors in calculating the PCB BAF. The agency used an equation to generate a total BAF that was a weighted average of the BAFs of the individual PCB congeners that appear in the Great Lakes. Rather than using the BAFs themselves, the agency used the logs of the BAFs of the various congeners. In calculating the weighted average, the agency added logs together as if they were base numbers, resulting in a much higher total than would have been accurate. This and other errors, petitioners argue, generated an inaccurately high BAF. The inaccurately high BAF in turn resulted in water quality criteria that were unnecessarily strict. Prior to oral argument the agency moved to [**82] remand for further [*1008] consideration of its use of the weighted-average equation. This court granted that motion. [8]

> 8 The agency has since published a new rule regarding the weighted-average BAF. *62 Fed. Reg. 11,724 (1997)*.

Petitioners' second argument is that the agency used an unnecessarily high Cancer Potency Factor (CPF) in determining the human health criterion. In the rulemaking, the agency relied on a study that found that the CPF was 7.7; petitioners contend that it should have relied on a later study that found that the CPF was actually 2.0. At oral argument the agency abandoned its defense of the 7.7 CPF. It announced that it intended to revise the PCB BAF in a subsequent rulemaking.

The agency also announced that, pending this further rulemaking, it will consider state proposals that use a CPF of 2.0 to be "consistent with" the Guidance.

Petitioners' final argument is that the agency relied on faulty data in its computation of the BAF. They are particularly critical of the agency's reliance on a BAF [**83] study conducted by Oliver and Niimi. The agency continues to contend that the data it used in computing the BAF is adequate for that purpose.

In light of the agency's conceded errors and announced intention to revise the PCB BAF, we vacate the challenged PCB criteria. This is not simply a matter of newly emerged evidence in a technologically advancing area, as in the challenge to the agency's continued use of the .06 ADE for mercury. Here the agency concedes that it applied a flawed mathematical process to an incorrect numerical base. There is little reason for us to enter a binding ruling on an administrative decision when the responsible agency has already determined that the decision under review is fundamentally flawed in two significant respects, and is already committed to agency revision in any event. By the same token, we do not address the petitioners' sole remaining argument. We see no profit in deciding today whether the agency's data is adequate. The agency may wish to reconsider its use of this data in the new PCB rulemaking.

* * *

For the preceding reasons we grant the petitions challenging the Guidance procedures governing mixing zones, the pollutant minimization [**84] program procedures, and the criteria for polychlorinated biphenyls. In all other respects, the petitions for review are denied.

So ordered.

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